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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/423,863	02/08/00	DONIE	F BMID9974US

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MARILYN L AMICK
ROCHE DIAGNOSTICS CORPORATION
9115 HAGUE ROAD BLDG D
PO BOX 50457
INDIANAPOLIS IN 46250-0457

EXAMINER	
LI, B	
ART UNIT	**PAPER NUMBER**
1648	12

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/423,863	DONIE ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17,19,21,23,25,29,30 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17, 19, 21, 23, 25, 29-30and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I directed to claims 15-17, 19, 21, 25, 30 and 32 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Group IV is not patentable distinct from Group I and should be rejoined as one group. Examiner reviewed argument and found that it is persuasive. Therefore, Group I and Group IV are rejoined.

The applicants are required to cancel the non-elected Groups II and III of claims 16, 18, 20, 22, 24, 26-28, 31 and 33.

Claims 15-17, 19, 21, 23, 25, 29-30 and 32 are considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17, 19, 21, 23, 25, 29-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-16, 19, 29 and 30 are vague and indefinite in that the metes and bonds of the antigen are not defined. The claims is interpreted in the light of the specification, however, it is well know that HIV-1 gp41 is the transmebrane domain the HIV-1 envelope protein that is the about 350 amino acids long, however, not all the region of the 350 amino acid sequence encode the antigenic peptide and can be utilized to detect the antibody against gp41. the claims should point out precisely which part of the sequence of HIV-1 gp41 is intended in the said claims. This effects the dependent claims 17, 21, 23, 25, and 32.

Claims 15 and 16 are also vague in that the use of a relative term of "derived". Since the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "derivation" has many interpretation, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore the claim is considered as indefinite.

Claim 16 is vague and indefinite the use of a recitation of "corresponding region". Since the specification does not provide a standard for ascertaining the definition or limitation of the

"corresponding region", one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore the claim is considered as indefinite.

Claims 16, 19, 21 and 25 are vague and indefinite in that the metes and bonds of the epitope regions are not defined. The claims are interpreted in the light of the specification, however, each epitope can range only 2-3 amino acids long. The claims should point out what are the exact sequence structure defined for the regions in the said claims.

Claim 21 is vague and indefinite in that the metes and bonds of the consensus sequence are not defined. The claims are interpreted in the light of the specification, however, the specification fails to define what precise sequence is referred as consensus sequence in the said claim. The claim should point out exactly which sequence is intended in the said claim.

Claims 17 and 23 are vague and indefinite in that the metes and bonds of the partial sequence thereof are not defined. The claims are interpreted in the light of the specification, however, The term "partial" in both claims is a relative and it can be defined by the said claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Is 50% partial sequence thereof intended or 80% partial sequence thereof intended. The claims should point out precisely which sequence is intended in the said claims.

Claims 15-16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: detecting the binding signal of said HIV antigen bound to the suspected antibody etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17, 19, 21, 23, 25, 29-30 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the anti-gp41 antibody of HIV-1 group M by using mixing two sequences selected from SEQ NO1-

11as a antigen peptide, does not reasonably provide enablement for using any or all sequences encoding the epitope I and II in any kind of mixture or length for detecting the antibody against gp41of HIV group M. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification of the present invention teaches that the anti-gp41 of HIV group M can be detected by using a mixture of three defined sequence antigen peptides selected from the SEQ No. 1-11 (two of the subtype of group M A to G plus one of the sequence from subtype O). The specification does not teach to use any or all sequences in the region of gp41 epitope I or II rather than the 11 defined sequence, in any kind of condition, such as mixture of more then three sequences, or any kind of length, can be used for detecting the anti-gp41 with any reasonable expectation of success. However, the scope of the claims read on an immunoassay method for detecting any or all antibody against gp41 from different subtype of HIV-1 group M with any or all kind of the mixture of the antigen from the epitope regions II and I of the consensus sequence of HIV-1 subtype D and subtype O.

Applicants have not taught what the defined sequence encoding the epitope regions II and I of the consensus sequence of HIV-1 subtype D and subtype O. The applicant is also reminded that the HIV-1 virus consist of many serotype and the virus is intend to mutate its genome naturally or in response to the drug therapy, therefore, new serotype may merge from time being. Therefore, the files is considered

unpredictable. Without adequent teaching, a person skill in the art would require to do large quantity of the work to full scope of the claimed invention.

Factors to be considered in the determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ 2d 1400 at 1404 (CAFC 1988). In the instant case, the examiner noted that 1) there are no working example, which suggest how to determine the censuses sequence encoding the epitope I and II of gp41 HIV serotype D and O and mix any or all of the sequences 2) the nature of the invention involved the complex and incompletely understood area of HIV antigen mutation 3) the state of the prior art shows that prior antigen epitope used for the detection has always been rendered a lot of false positive or false negative result 4) the relative skill of those in the art is commonly recognized as quite high, and 5) the lack of predictability in the field.

In view of all of the above, it is concluded without an adequate teaching whether any or all censuses sequence mixture can be used as an antigen peptide for detecting anti-gp41 antibody of any or all subtype of HIV-1 group M, the skilled artisan would not have a reasonable expectation of success in making and using the products encompassed by the instants methods because there are not limitations as to the infinity variety of mixture of undefined consensus sequence encoding the epitope I and II of the gp41 in HIV-1 subtype D and O.

Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-17, 19, 21, 23, 25, 29-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Ley et al. (WO 93/18054) and Chamaret et al. (FR2730493-A1).

The present invention is drawn to an immunoassay method for detecting an antibody against HIV gp41 antigen by using a mixture of an antigen peptide of gp41 from different HIV-1 subtype of the group M, more preferentially the said peptide antigen of gp41 is from HIV-1 subtype D isolate corresponding to a sequence selected from the group consisting of SEQ ID Nos. 1 to 11, wherein the peptide is about 16 amino acids in length or preferable has minimal length of 7 amino acids and is synthesized as biotinylated or digoxigenylated peptide.

Chamaret et al. teaches to use a 34 amino acids polypeptide of gp41 derived from the HIV-1 group M-subtype D and has 100% homology to the SEQ No. 6, which can be used for the detecting HIV-1 gp41 antibody by an immunoassay method (Claim 4). Chamaret et al. does not teach to use a mixture of peptide antigens for detecting variable antibodies against gp41 from different subtypes of HIV-1 group M.

De Leys et al. teaches a method for using a mixture of biotinylated peptides for detecting an antibody against HIV-1 gp41, wherein one of the biotinylated peptide antigens has 100% homology to SEQ NO. 3 of the current application (claim 4, SEQ No. 6, pp. 90-98 and example 11), wherein the length of the peptide can be more preferably from 4-25 amino acids (lines 2-14, pp. 7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references Chamaret et al. and De Leys et al. to reduce the length of the antigen peptide disclosed in the cited references to the range of 4 to 25 and further use the method taught by De Leys et al. to mix the biotinylated the peptides for detection variable antibodies against the transmenbranse domain of the envelope protein gp41 of HIV-1 different subtype infection without unexpected results. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

Baoqun Li

March 23, 2001

ALI R. SALIMI
PRIMARY EXAMINER